

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

| | | |
|-----------------------------|---|----------------------------|
| In re Application of | : | Customer Number: 31824 |
| Edward Z. NOWAK, et al. | : | Confirmation Number: 6240 |
| Application No.: 10/701,293 | : | Tech Center Art Unit: 1618 |
| Filed: November 03, 2003 | : | Examiner: Humera N. Sheikh |
| For: DELIVERY CAPSULES | : | |

TRANSMITTAL OF SUBSTITUTE APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


Sir:

Submitted herewith is Appellant's Substitute Appeal Brief in response to the Notification of Non-Compliant Appeal Brief issued December 15, 2008, which indicated that the Status of Claims in the November 21, 2008 Appeal Brief did not contain a statement of the status of all claims. This section has been corrected in the Substitute Appeal Brief submitted herewith to include a statement that claims 1 to 14 were previously cancelled.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due under 37 C.F.R. 1.17 and 41.20, and in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



Joshua M. Nelson
Registration No. 55,487

18191 Von Karman Ave., Suite 500
Irvine, CA 92612-7108
Phone: 949.851.0633 JMN:lm
Facsimile: 949.851.9348
Date: January 13, 2009

**Please recognize our Customer No. 31824
as our correspondence address.**

Docket No.: 061170-0194

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

| | | |
|-----------------------------|---|----------------------------|
| In re Application of | : | Customer Number: 31824 |
| | : | |
| Edward Z. NOWAK, et al. | : | Confirmation Number: 6240 |
| | : | |
| Application No.: 10/701,293 | : | Tech Center Art Unit: 1618 |
| | : | |
| Filed: November 03, 2003 | : | Examiner: Humera N. Sheikh |
| | : | |
| For: DELIVERY CAPSULES | : | |

SUBSTITUTE APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is submitted in support of the Notice of Appeal filed July 22, 2008, wherein Appellant appeals from the Primary Examiner's rejection of claims 15 to 50.

TABLE OF CONTENTS

| | | |
|-------|---|----|
| I. | REAL PARTY IN INTEREST..... | 3 |
| II. | RELATED APPEALS AND INTERFERENCES | 3 |
| III. | STATUS OF CLAIMS | 3 |
| IV. | STATUS OF AMENDMENTS..... | 3 |
| V. | SUMMARY OF CLAIMED SUBJECT MATTER..... | 3 |
| VI. | GROUND OF REJECTION TO BE REVIEWED BY APPEAL..... | 5 |
| VII. | ARGUMENT..... | 5 |
| VIII. | CONCLUSION..... | 8 |
| IX. | CLAIMS APPENDIX | 9 |
| X. | EVIDENCE APPENDIX..... | 13 |
| XI. | RELATED PROCEEDINGS APPENDIX..... | 14 |

I. REAL PARTY IN INTEREST

This application is assigned to BioProgress Technology International, Inc. by assignment recorded on June 4, 2007, at Reel 019408, Frame 0768.

II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals and interferences.

III. STATUS OF CLAIMS

Claims 15 to 52 are pending in this application, with claims 1 to 14 having previously been cancelled. In the Office Action mailed on January 22, 2008, claims 15 to 50 were finally rejected under 35 U.S.C. § 103(a), and claims 51 and 52 were finally rejected under 35 U.S.C. § 112, second paragraph. The 35 U.S.C. § 112, second paragraph, rejections of claims 51 and 52 were withdrawn in the Advisory Action dated July 28, 2008. It is from the final rejection of claims 15 to 50 that this appeal is taken. Claims 15 to 50 are copied in the Appendix to this Appeal Brief.

IV. STATUS OF AMENDMENTS

A Response to Final Office Action was filed on June 23, 2008, subsequent to the final Office Action mailed on January 22, 2008. No claim amendments were made in the June 23, 2008 Response to Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

An aspect of the invention, per independent claim 15, is a delivery capsule. The capsule has at least two separate chambers (see ¶ [0038] of the written description). The capsule includes a dividing wall or septum (see ¶ [0038] of the written description) defining in part two separate chambers (see ¶ [0038] of the written description). The dividing wall or septum comprises two layers of material

(see ¶ [0023] of the written description) adhered together with an adhesive material (see ¶ [0024] of the written description).

Another aspect of the invention, per independent claim 46, is a method of encapsulation. The method comprises supplying two films of material capable of deforming plastically on heating (see ¶ [0056] of the written description) and/or when partially solvated (see ¶ [0021] of the written description). The method further comprises heating the films (see ¶ [0056] of the written description) and/or applying solvent (see ¶ [0021] of the written description). The method further includes forming the films into suitably shaped capsule portions (see ¶¶ [0054]-[0056] of the written description) and supplying respective substances to be encapsulated to capsule portions of each film (see ¶ [0058] of the written description). The method further comprises supplying a respective film of a dividing septum material to each of the filled capsule portions (see ¶ [0059] of the written description) and sealing the capsule portions and septum material together to form a capsule having at least two separate chambers (see ¶¶ [0060]-[0062] of the written description).

Another aspect of the invention, per independent claim 47, is an encapsulation apparatus. The apparatus comprises means for supplying two films of material to an encapsulation unit (see ¶ [0056] of the written description). The apparatus further comprises means for plastically deforming each film to form suitably shaped capsule portions (see ¶¶ [0054]-[0056] of the written description) and means for supplying respective substances to be encapsulated to the respective capsule portions of each film (see ¶ [0058] of the written description). The apparatus further comprises means for supplying a respective film of dividing septum material to each of the filled capsule portions (see ¶ [0059] of the written description) and means for sealing together the capsule portions and septum material to produce a capsule having at least two separate chambers (see ¶¶ [0060]-[0062] of the written description).

VI. GROUND OF REJECTION TO BE REVIEWED BY APPEAL

1. Claims 15 to 50 were rejected under 35 U.S.C. § 103(a) over European Patent Application No. 0 211 079 (“Ueda”) in view of International Patent Application No. WO 97/35537 (“Brown”).

VII. ARGUMENT

1. Rejection of claims 15 to 50 under 35 U.S.C. § 103(a) over Ueda in view of Brown

The Examiner’s Position:

The Examiner maintains that “[w]hile Ueda does not teach a two-layered material, but rather teaches a single film, the capsule of Ueda is functionally equivalent to the capsule being claimed herein.” July 28, 2008 Advisory Action, p. 2. The Examiner has repeatedly asserted that “Applicants have not demonstrated any significant patentable distinction between the Ueda delivery capsule and the instant delivery capsule.” January 22, 2008 Office Action, pp. 4-5.

Appellant’s Position:

As conceded by the Examiner, neither Ueda nor Brown discloses the features of the claimed invention, particularly with respect to at least the features of (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material (as in claim 15) and (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions (as in claims 46 and 47).

Prima facie obviousness

Ueda is seen to be directed to a multi-chamber capsule divided by *a single film* into a plurality of chambers. *See, e.g.*, Ueda p. 4, ll. 8-20; p. 9, ll. 7-25. Brown is seen to be generally directed to a method of encapsulation for forming capsules, in which capsules are formed by bringing together two opposed capsule halves in the shape of open hemispheres, such that they form *a single undivided*

chamber. *See, e.g.*, Brown, pp. 5-6. Nowhere is Ueda or Brown seen to disclose or suggest a septum or a dividing wall of any kind, let alone a dividing wall or septum having two layers of material adhered together with an adhesive material.

Accordingly, the applied references, whether taken alone or in combination, are not seen to disclose or suggest the features of independent claims 15, 46 and 47, particularly with respect to at least the features of (i) a dividing wall or a septum having two layers of material adhered together with an adhesive material, and (ii) supplying a respective film of a dividing septum material to each of two filled capsule portions.

As has been repeatedly stressed by the Appellant, “[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” MPEP § 2143.03; *see also In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). In this respect, the Examiner has conceded that Ueda and Brown do not teach the particular claim feature of a dividing wall or a septum having two layers of material. Accordingly, as this claim feature is nowhere taught in or suggested in the cited references, the outstanding 35 U.S.C. § 103(a) rejection of claims 15 to 50 fails to meet the standard for *prima facie* obviousness.

Explicit analysis supporting obviousness rejection

The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), stated that “ ‘[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.’ ” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 at 1396 (2007). The MPEP echoes this sentiment, indicating in the Examination Guidelines for Determining Obviousness under 35 U.S.C. § 103 “The key to supporting any rejection under 35 U.S.C.

103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.”

MPEP § 2141. Despite this clear guidance, the Examiner has repeatedly supported the outstanding obviousness rejection with conclusory statements such as “it is the position of the Examiner that the soft capsules of Ueda entail a similar function and purpose as that of the instantly claimed delivery capsule” (January 22, 2008 Office Action, p.4); “[i]t remains the position of the Examiner that the two-layered septum film being claimed by Applicant does not patentably define and distinguish over the explicit reference teachings of the art. The capsule of Ueda is functionally equivalent to the capsule of the instant invention” (January 22, 2008 Office Action, p. 8); and “the capsule of Ueda is functionally equivalent to the capsule being claimed herein” (July 28, 2008 Advisory Action, p. 2).

Improper Burden Shifting

The Examiner’s contention that “[a]pplicants have not demonstrated any significant patentable distinction between the Ueda delivery capsule and the instant delivery capsule” (January 22, 2008 Office Action, pp. 4-5) constitutes premature and inappropriate burden shifting. In this regard, the Examiner has failed to make a *prima facie* case of obviousness, as all of the claim limitations are neither taught nor suggested by the prior art, as admitted by the Examiner and as set forth in greater detail above. Accordingly, the Office Action’s requirement that Applicants demonstrate a “significant patentable distinction” between the cited reference and the claimed invention constitutes an inappropriate and premature attempt to shift onto Applicants the burden of rebutting an obviousness showing that has yet to be made by the Office. *See, e.g.*, MPEP § 2145 (“**If** a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case.” (emphasis added)). The Examiner’s contention that “[a]bsent any evidence or showing of unexpected results obtained by the instant invention, the teachings of the

prior art of record are sufficient to meet the limitations of the instant capsule” (January 22, 2008 Office Action, p. 8) further exemplify this improper, premature burden shifting.

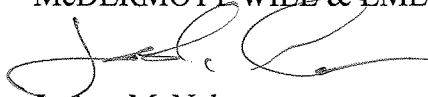
VIII. CONCLUSION

Based upon the arguments submitted above, Appellant respectfully submits that the Examiner’s rejection of claims 15 to 50 under 35 U.S.C. § 103(a) are not legally viable. Appellant, therefore, respectfully solicits the Honorable Board to reverse the Examiner’s rejections of claims 15 to 50 under 35 U.S.C. § 103(a).

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502203 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



Joshua M. Nelson
Registration No. 55,487

18191 Von Karman Ave., Suite 500
Irvine, CA 92612-7108
Phone: 949.851.0633 JMN:lm
Facsimile: 949.851.9348
Date: January 13, 2009

**Please recognize our Customer No. 31824
as our correspondence address.**

IX. CLAIMS APPENDIX

15. (Previously presented) A delivery capsule having at least two separate chambers, the capsule including a dividing wall or septum defining in part two separate chambers, wherein the dividing wall or septum comprises two layers of material adhered together with an adhesive material.

16. (Previously presented) A capsule according to claim 15, wherein each chamber contains a different material.

17. (Previously presented) A capsule according to claim 15, wherein each chamber contains a metered dose of a material.

18. (Previously presented) A capsule according to claim 16, wherein each chamber contains a metered dose of a material.

19. (Previously presented) A capsule according to claim 15, wherein the dividing wall or septum comprises a median wall symmetrically arranged to form two chambers of similar size and shape.

20. (Previously presented) A capsule according to claim 16, wherein the dividing wall or septum comprises a median wall symmetrically arranged to form two chambers of similar size and shape.

21. (Previously presented) A capsule according to claim 17, wherein the dividing wall or septum comprises a median wall symmetrically arranged to form two chambers of similar size and shape.

22. (Previously presented) A capsule according to claim 15, formed from a heat-sealable material that is capable of deforming plastically on heating and/or when partially solvated.

23. (Previously presented) A capsule according to claim 16, formed from a heat-sealable material that is capable of deforming plastically on heating and/or when partially solvated.

Application No. 10/701,293

24. (Previously presented) A capsule according to claim 17, formed from a heat-sealable material that is capable of deforming plastically on heating and/or when partially solvated.

25. (Previously presented) A capsule according to claim 19, formed from a heat-sealable material that is capable of deforming plastically on heating and/or when partially solvated.

26. (Previously presented) A capsule according to claim 22, wherein the capsule is formed from one or more materials selected from the group consisting of: hydroxy propyl methyl cellulose, pectin, polyethylene oxide, polyvinyl alcohol, alginate, polycaprolactone, and gelatinised starch based materials.

27. (Previously presented) A capsule according to claim 26, wherein at least part of the capsule material carries a coating.

28. (Previously presented) A capsule according to claim 15, wherein said at least two chambers are designed to release their contents under similar circumstances.

29. (Previously presented) A capsule according to claim 16, wherein said at least two chambers are designed to release their contents under similar circumstances.

30. (Previously presented) A capsule according to claim 17, wherein said at least two chambers are designed to release their contents under similar circumstances.

31. (Previously presented) A capsule according to claim 19, wherein said at least two chambers are designed to release their contents under similar circumstances.

32. (Previously presented) A capsule according to claim 22, wherein said at least two chambers are designed to release their contents under similar circumstances.

33. (Previously presented) A capsule according to claim 26, wherein said at least two chambers are designed to release their contents under similar circumstances.

Application No. 10/701,293

34. (Previously presented) A capsule according to claim 27, wherein said at least two chambers are designed to release their contents under similar circumstances.

35. (Previously presented) A capsule according to claim 15, wherein said at least two chambers are designed to release their contents under different circumstances.

36. (Previously presented) A capsule according to claim 16, wherein said at least two chambers are designed to release their contents under different circumstances.

37. (Previously presented) A capsule according to claim 17, wherein said at least two chambers are designed to release their contents under different circumstances.

38. (Previously presented) A capsule according to claim 19, wherein said at least two chambers are designed to release their contents under different circumstances.

39. (Previously presented) A capsule according to claim 22, wherein said at least two chambers are designed to release their contents under different circumstances.

40. (Previously presented) A capsule according to claim 26, wherein said at least two chambers are designed to release their contents under different circumstances.

41. (Previously presented) A capsule according to claim 27, wherein said at least two chambers are designed to release their contents under different circumstances.

42. (Previously presented) A capsule according to claim 28, wherein said at least two chambers are designed to release their contents under different circumstances.

43. (Previously presented) A capsule according to claim 35, wherein different chambers of the capsule are defined at least in part by different materials.

44. (Previously presented) A capsule according to anyone of claims 15, 16, 17, 19, 22, 26, 27, 28, or 35, wherein the capsule is formed at least in part from hydroxy propyl methyl cellulose.

45. (Previously presented) A capsule according to claim 44, wherein at least part of the hydroxy propyl methyl cellulose is coated with alginate.

46. (Previously presented) A method of encapsulation comprising supplying two films of material capable of deforming plastically on heating and/or when partially solvated; heating the films and/or applying solvent; forming the films into suitably shaped capsule portions; supplying respective substances to be encapsulated to capsule portions of each film; supplying a respective film of a dividing septum material to each of the filled capsule portions; and sealing the capsule portions and septum material together to form a capsule having at least two separate chambers.

47. (Previously presented) Encapsulation apparatus comprising means for supplying two films of material to an encapsulation unit; means for plastically deforming each film to form suitably shaped capsule portions; means for supplying respective substances to be encapsulated to the respective capsule portions of each film; means for supplying a respective film of dividing septum material to each of the filled capsule portions; and means for sealing together the capsule portions and septum material to produce a capsule having at least two separate chambers.

48. (Previously presented) The method of claim 46, wherein the dividing wall or septum comprises two layers of material.

49. (Previously presented) The encapsulation apparatus of claim 47, wherein the dividing wall or septum comprises two layers of material.

50. (Previously presented) A capsule formed by the method of claim 46.

X. EVIDENCE APPENDIX

No extrinsic evidence is relied upon in this appeal.

XI. RELATED PROCEEDINGS APPENDIX

Appellant is unaware of any related appeals and interferences.

ORC 453956-1.061170.0194